REMARKS

In response to the Office Action mailed July 22, 2009, Applicants respectfully request the Examiner to reconsider the above-captioned Application in view of the foregoing amendments and the following remarks.

I. Summary of the Office Action

In the July 22, 2009 Office Action, Claims 18, 23, 27, 33-41, 43, 44, 46, 50-59, and 61-72 stand rejected. Claims 18, 23, 33-41, 43-44, 46, 50-59, and 61-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,527,312 issued to Ray (hereinafter "Ray") in view of U.S. Patent No. 5,989,255 issued to Pepper et al. (hereinafter "Pepper"). In addition, Claim 26 stands objected to as being dependent upon a rejected base claim. Further, Claims 45, 47-49, and 60 stand allowed.

II. Summary of the Amendment

By this paper, Applicants have amended Claim 44. Accordingly, Claims 18, 23, 26, 33-41, and 43-72 are currently pending in the present Application. By this paper, Applicants respond to the Examiner's comments and rejections made in the July 22, 2009 Office Action. Applicants respectfully submit that the present Application is in condition for allowance.

III. Allowable Subject Matter

Applicants gratefully note that Claims 45, 47-49, and 60 stand allowed by the Examiner.

IV. Traversal of Rejections under 35 U.S.C. § 103(a), Based on Ray in view of Pepper

In the Office Action, Claims 18, 23, 33-41, 43-44, 46, 50-59, and 61-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ray in view of Pepper. Applicants respectfully traverse the expedite prosecution of this Application. Accordingly, Applicants respectfully request that the rejection of Claims 18, 23, 33-41, 43-44, 46, 50-59, and 61-72 be withdrawn and that these claims be indicated as allowable over the art of record.

A. Review of Ray and Pepper

Ray is directed to a screw used in a spinal fixation system. *See* Ray, Abstract. Ray points out that translaminar screws are inadequate to fixate an intervertebral joint in performing spinal fusion when a patient has undergone a laminectomy. Because of the laminectomy, the lamina of the superior vertebra is generally weak, and the translaminar screws can cause breakage in the lamina, thus destabilizing the fixated joint. As such, Ray discloses a method of spinal fixation in which pairs of fixation bars are used to stabilize pairs of screws to fixate the intervertebral joint when a laminectomy has been performed. In particular, each screw passes through an aperture of a fixation bar that is hooked over and around the pedicle of the superior vertebra. *See id.* at col. 2, line 50 – col. 3, line 9.

The first screw is advanced on the left side of the sagittal plane through the lamina of a superior vertebra and into the left base of the transverse process of an inferior vertebra, thereby fixing the position of the first fixation bar. *See id.* at col. 2, lines 35-41. Further, the second screw it is advanced on the right side of the sagittal plane through the lamina of the superior vertebra into the right base of the transverse process of the inferior vertebra, thereby fixing the position of the second fixation bar. *See id.* at col. 2, lines 41-47. These features are illustrated below in Figure 1 of Ray.

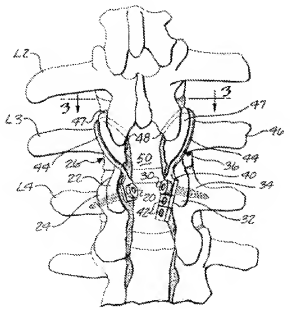

Fig. 1.

In order to minimize lateral or transverse movement of the screw relative to the longitudinal axis of the screw, Ray uses the fixation bars. The fixation bars form a hook that extends over and around the adjacent pedicle to secure the bar from movement in an inferior direction. *See id.* at col. 3, lines 3-6.

Moreover, with respect to Pepper, Pepper is directed to an orthopedic bone screw apparatus and a method of implantation. *See* Pepper, Abstract. The bone screw apparatus of Pepper is capable of applying axial or secondary compression.

B. The Combination is Improper Because there is No Articulated Reason, Recognized Problem, or Rational Underpinning to Combine the References as Proposed

In *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), the Supreme Court re-iterated the framework set forth in *Graham v. John Deere Co. of Kansas City*, 86 S. Ct. 684 (1966) for applying 35 U.S.C. § 103. The Court noted that the Federal Circuit's teaching, suggestion, motivation test provided a "helpful insight" and cautioned that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *See KSR Int'l Co.*, 127 S.Ct. at 1741. As such, there must be some "articulated reasoning with some rational underpinning" showing a "reason to combine" the elements of the prior art. *See id.* at 1740-1 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

The USPTO confirmed this in the M.P.E.P. and in its post-*KSR* examination guidelines.[1] *See* MPEP 2142. The Court in *KSR* also indicated that the motivation to combine test applied by the Federal Circuit in *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006) was consistent with the principles of *Graham*. See *KSR Int'l Co.*, 127 S.Ct. at 1741-3. Post-*KSR*, The Federal Circuit has consistently required a showing of some articulated reason or motivation to combine references. See, e.g., *In re Translogic, Inc.*, 504 F.3d 1249 (Fed. Cir. 2007); see also *Takeda Chemical Industries, Ltd. v. Alphapharm PTY., Ltd.*, 492 F.3d 1350, 1356-7 (Fed. Cir. 2007).

[1] Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, Patent and Trademark Office, Federal Register Vol. 72 No. 195 ("Post-KSR Examination Guidelines"), 57528-9.)

The Office Action has not provided "articulated reasoning with some rational underpinning" to modify Ray in the manner proposed, and a person of skill has no such reason to modify Ray as proposed. Although attempting to articulate a reason to combine the references, the Office Action merely indicates that a person of skill would substitute the bone screw of Ray with the screw of Pepper, as the "mere substitution of one functionally equivalent device for another." *See* Office Action, page 3.

However, the screws disclosed in Ray and Pepper are not functional equivalents. Certainly, there is no way the screw disclosed in Ray could perform the function that the Pepper screw performs. The screw disclosed in Ray cannot provide secondary compression. The screw disclosed in Ray is a threaded elongate body with a head that is configured to receive a wrench, such as an Allen wrench. *See id.* at col. 3, lines 10-13 and Figures 1, 2, and 4. Further, although the method disclosed in Ray provides a method of fixing a fixation bar to stabilize adjacent vertebrae, Ray provides no teaching or other disclosure of how the screws are able to provide sufficient compression across the intervertebral joint in any situation, much less secondary compression. Furthermore, Ray fails to teach or otherwise disclose how the distal tip of the screw is prevented from exiting the transverse process of the inferior vertebra if the screws need to be further rotated to provide additional compression.

Further, the Pepper screw is not the functional equivalent of the Ray screw, and would not be considered as such by a person of skill in the art. The Pepper screw is intended for axial compression, must be broken before it is finally implanted, and is overall far more complex than the Ray screw. These functions are completely different from those of the Ray screw and there is no reason provided or ascertainable as to why a person of skill would seek to use these features in the Ray method.

Moreover, a combination of Ray and Pepper is not proper because a person of skill would not seek to apply axial compression along the axis of the screw disclosed in Ray. Ray is concerned about minimizing lateral or transverse movement of the screw relative to the longitudinal axis of the screw—not axial or longitudinal movement of the screw. That is why Ray discloses the use of the fixation bars, to minimize lateral movement of the screws. The fixation bars form a hook that extends over and around the adjacent pedicle to secure the bar from movement in an inferior direction. *See id.* at col. 3, lines 3-6. This arrangement resists

lateral or transverse "toggling" of the screw, as can be appreciated by reference to Figure 1 in Ray.

In this regard, the Office Action fails to provide any articulated reason or argument as to why a person of skill would substitute the unnecessarily difficult and complex Pepper screw in the Ray method. There is no argument or suggestion in the Office Action that a person of skill would be motivated or believe that any of the additional features provided by Pepper would be necessary or an obvious variant in the Ray method. A person of skill in the art would see no reason to combine the teachings of Pepper and Ray.

Accordingly, Applicants respectfully submit that the combination of Ray and Pepper is improper at least because there is no "articulated reasoning with some rational underpinning" showing a "reason to combine" the elements of Ray with Pepper.

C. The Combination of Ray and Pepper Does Not Disclose Each and Every Feature of Claims 18, 23, 33-41, 43-44, 46, 50-59, and 61-72

Even assuming arguendo that the combination of Ray and Pepper were proper, the combination of the teachings of Pepper and Ray do not teach or otherwise provide any reason to provide each of the features recited in the claims of the present Application. Instead, a combination of Pepper and Ray would produce a modified Ray method in which the Pepper compression screw passes into the lamina of a laminectomy patient, extends into the transverse process, and is linked with the fixation bar, which does not render the claimed methods obvious.

Applicants initially note that while Ray provides benefits related to post-laminectomy spinal stabilization, the method disclosed in Ray is directed at solving a problem that is generally unrelated to the problems solved through the present Application. It is not surprising then, that the Ray method does not disclose each and every feature or contemplate the advantages provided by the methods disclosed in the present Application.

Applicants note that the final Office Action indicates that, Ray discloses a method wherein "the screw is advanced through a first vertebra into the pedicle of a second vertebra." *See* Office Action, page 3. Applicants respectfully traverse this interpretation of Ray and submit that a person of skill in the art would understand that Ray discloses that the screws actually *avoid the pedicle*—that the screws are advanced into the transverse process of the inferior vertebra, which is functionally and structurally different from the pedicle.

Indeed, Ray specifically discloses that the screws are advanced through the lamina of the superior vertebra and into the transverse process of the inferior vertebra. *See id.* at col. 2, lines 35-47. A person of skill would not construe this disclosure as teaching or otherwise providing any reason to advance a bone fixation device, such as that disclosed in the present Application, through the facet of the superior vertebra and into the pedicle of the inferior vertebra, as generally recited in the claimed methods. In contrast to Ray, some claims of the present Application recite that the bone anchor extends into the pedicle of the inferior vertebra. Neither Ray nor Pepper disclose this feature of Claims 18, 44, and 59.

Nor does Pepper suggest modifying Ray in a manner that would produce the method recited in Claims 18, 44, or 59.

In contrast, various claims of the present Application seek to apply compression or prevent movement along the axial or longitudinal direction of the fixation device. Thus, Ray and Pepper fail to teach or otherwise disclose any of the claimed methods of the present Application, including the steps of advancing the proximal anchor to apply compression between the facet of the first vertebra at the second vertebra or "mechanically decoupling the second portion from the first portion after the proximal anchor is advanced distally along the fixation device," as recited in Claim 18.

Therefore, for at least these reasons, Applicants respectfully request that the Examiner withdraw the rejection of Claims 18, 23, 33-41, 43-44, 46, 50-59, and 61-72 and indicate at that these claims are allowable over the art of record.

D. The Claims of the Present Application Represent a Solution to a Longfelt, but Unmet Need

Moreover, as discussed in the Declaration of Atiq Durrani submitted herewith, the Examiner is not appreciating the long-present problem or the unique solution provided and described in the '193 Application. At the time of the invention, there was a long felt, but unresolved need "for an orthopedic fixation device for spinal fixation with improved locking force, which resists migration and rotation, and which can be easily and rapidly deployed within the spine." Present Application, ¶ [0009].

As discussed above, prior art transfacet screws failed to provide sufficient compression across the joint of the vertebrae. For example, as in Ray, many of these compression screws simply provided a first level of compression that was achieved by rotating the bone anchor into the inferior vertebra. However, because the bone anchor could only travel a limited distance within the inferior vertebra, one of two unacceptable outcomes was created in many cases: either the bone anchor broke through to the exterior of the inferior vertebra or the bone anchor was not advanced far enough to provide sufficient compression across the intervertebral joint.

Although this problem was recognized since the 1960s, no one has developed a fixation device or procedure to solve these problems until the present Application. In other words, despite being aware of these issues and competitions, no one in the medical community was able to resolve these issues for nearly 40 years. Moreover, as noted above, transfacet fixation had obvious theoretical advantages over traditional pedicle screw fixation techniques. Specifically, transfacet fixation could be done in much more minimally invasive manner as compared to traditional pedicle screw fixation. Now, given the claimed methods of the present Application, a surgeon can (1) achieve significantly more compression across the intervertebral joint than ever possible using the prior art compression screws, (2) do so without rotating the bone anchor from a dead center embedded position in the pedicle of the inferior vertebra and (3) achieve truly minimally invasive posterior fixation.

The claims of the present Application solve this long felt, but unmet need by providing a method of spinal fixation, for example, according to: Claim 18 which comprises in part, "advancing the bone anchor of the fixation device through a facet of a first vertebra to position a distal tip of the bone anchor within a pedicle of a second vertebra," advancing the proximal anchor over the body to apply compression between the first and second vertebrae and "mechanically decoupling the second portion from the first portion after the proximal anchor is advanced distally along the fixation device"; Claim 44 which comprises in part, "advancing the distal anchor of the fixation device through a facet of a first vertebra and into a pedicle of a second vertebra" and moving the proximal anchor distally over the body "thereby applying compression between the first and second vertebra"; and Claim 59 which comprises in part, "advancing the distal anchor of the fixation device through a facet of a first vertebra and into a

pedicle of a second vertebra" and axially shortening the fixation device to "thereby applying compression between the first and second vertebra."

As discussed in the '193 Application, such methods can be performed by providing a fixation device whose distal tip or bone anchor can first be positioned within the pedicle of the inferior vertebra, and whose proximal anchor can subsequently be distally advanced along the device to provide secondary compression across the intervertebral joint. Thereafter, the surgeon can detach or decouple a second portion of the device from a first portion thereof. Thus, the claimed methods can be used provide compression that is far superior to what was available using prior art methods. Moreover, no publications or products beside the present patent Application that addresses this problem as described in the present patent Application.

In August 2005, Interventional Spine began the first commercial implementation of the methods claimed in the '193 Application. The commercial product used in these methods was designated Bone Lok. The Bone Lok has an elongate body with a distal bone anchor, a proximal anchor that advances along the elongate body to provide compression, and first and second portions of the elongate body that can be mechanically decoupled.

Further, as attested by Atiq Durrani, the spinal fixation procedures conducted as disclosed in the present Application have been the subject of several laudatory statements.

Therefore, Applicants respectfully submit that the claims of the present Application are novel and nonobvious in light of the prior art and respectfully request the Examiner to indicate the same.

V. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not

reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

VI. Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present Application's assignee.

Serial Number	Title	Filed
11/199,516	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	8/8/2005
11/444,103	LOCKING PLATE FOR BONE ANCHORS	5/31/2006
11/623,270	METHOD AND APPARATUS FOR SPINAL FIXATION	1/15/2007
11/099,431	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	4/5/2005
11/623,290	METHOD AND APPARATUS FOR SPINAL FIXATION	1/15/2007
11/099,431	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	4/5/2005
11/036,781	GUIDANCE SYSTEM FOR SPINAL STABILIZATION	1/14/2005
11/056,991	METHOD AND APPARATUS FOR SPINAL STABILIZATION	07/20/2005
11/296,881	METHOD AND APPARATUS FOR SPINAL STABILIZATION	12/08/2005
11/050,975	METHOD AND APPARATUS FOR SPINAL FUSION	2/4/2005
10/830,631	METHOD AND APPARATUS FOR BONE FIXATION WITH SECONDARY COMPRESSION	4/23/2004
12/134,886	METHOD AND APPARATUS FOR SPINAL STABILIZATION	6/06/2008

VII. CONCLUSION

Applicants respectfully submit that the above rejections and objections have been overcome and that the present Application is now in condition for allowance. Therefore, Applicants respectfully request that the Examiner indicate that Claims 18, 23, 33-41, 43-44, 46, 50-59, and 61-72 are now acceptable and allowed. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present Application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claim and drawings in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: November 17, 2009

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